Department of Veterans Affairs

Office of Inspector General

Review of Open Market Purchases under VA's Pharmaceutical Prime Vendor Contract Number V797P-1020 Awarded to McKesson Corporation

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TABLE OF CONTENTS

Acronyms and Abbreviations i

Executive Summary ii

Introduction

Purpose and Objectives 1
Background on PPV Program 1
Overall Scope and Methodology 5

Results and Recommendations 7

OBJECTIVE 1: Determine total VA purchases of open market products through the PPV during Fiscal Year (FY) 2011. Of the open market purchases, determine the total pharmaceuticals and medical/surgical supplies purchased. 7

OBJECTIVE 2: Determine total VA purchases of open market products of on contract pharmaceuticals. Determine why on contract pharmaceutical products were purchased open market. Ascertain the monetary impact, if any, of purchasing on contract pharmaceuticals products open market. 9

OBJECTIVE 3: Determine why non-contract pharmaceuticals were purchased open market. Determine if comparable pharmaceuticals were on contract and/or available for any non-contract open market purchases and, if so, determine why non-contract products were purchased instead of on contract products. 13

OBEJCTIVE 4: Identify patterns and trends in VA's open market pharmaceutical purchases. 15

OBJECTIVE 5: Determine whether there were any controls in place to prevent VA open market purchases through the PPV and to identify such purchases in a more timely and thorough manner. Determine whether the November 2011 policy changes were effective in limiting the amount of open market purchases through the PPV. Determine whether the new PPV contract (effective in August 2012) will effectively limit the amount of open market purchases through the PPV. 16

OBJECTIVE 6: Determine whether VA was initially charged the correct contract prices for purchases through the PPV. If not, determine whether the PPV later corrected the prices either independently or in response to PBM's price adjudications. 21

OBJECTIVE 7: Determine whether VA's open market purchases violated procurement laws and regulations and, if so, determine to what extent such violations occurred. 23

OBJECTIVE 8: Determine whether VA purchases complied with the Trade Agreements Act. 23

Summary

Conclusions 25
Recommendations 26

Appendixes

A. Principal Executive Director for Acquisition, Logistics, and Construction Comments 28
B. Under Secretary for Health Comments 37
C. OIG Contact and Staff Acknowledgements 38
D. Report Distribution 39

ACRONYMS AND ABBREVIATIONS

BOP	Bureau of Prisons
BPA	Blanket Purchase Agreement
BRS	Business Resource Support
CMOP	Consolidated Mail Outpatient Pharmacy
DoD	Department of Defense
FAR	Federal Acquisition Regulation
FCP	Federal Ceiling Price
FSS	Federal Supply Schedule
FY	Fiscal Year
IHS	Indian Health Service
INS	Immigration and Naturalization Service
NAC	National Acquisition Center
NC	National Contract
NDC	National Drug Code
Non-FAMP	Non-Federal Average Manufacturer's Price
OGA	Other Government Agency
OIG	Office of Inspector General
PBM	Pharmacy Benefits Management
PHS	Public Health Service
PMRS	Program Management and Resource Support
PPV	Pharmaceutical Prime Vendor
SVH	State Veterans Homes
TAA	Trade Agreements Act
VA	Veterans Affairs
VHA	Veterans Health Administration
WAC	Wholesale Acquisition Cost
WBPG	WAC Based Priced Generics

EXECUTIVE SUMMARY

Introduction – Review Objectives

At the request of the VA Secretary and the House Committee on Veterans' Affairs, we conducted a review of open market pharmaceutical purchases under VA's Pharmaceutical Prime Vendor Contract (PPV) Number V797P-1020 awarded to McKesson Corporation. In order to address the concerns identified in the Committee's letter dated December 20, 2011, to the Inspector General, we developed the following eight objectives.

1. Determine total VA purchases of open market products through the PPV during fiscal year (FY) 2011.[1] Of the open market purchases, determine the total pharmaceuticals and medical/surgical supplies purchased.
2. Determine total VA purchases of open market products of on contract pharmaceuticals. Determine why on contract pharmaceutical products were purchased open market. Ascertain the monetary impact, if any, of purchasing on contract pharmaceutical products open market.
3. Determine why non-contract pharmaceuticals were purchased open market. Determine if comparable pharmaceuticals were on contract and/or available for any non-contract open market purchases and, if so, determine why non-contract products were purchased instead of on contract products?
4. Identify patterns and trends in VA's open market pharmaceutical purchases.
5. Determine whether there were any controls in place to prevent VA open market purchases through the PPV and to identify such purchases in a more timely and thorough manner. Determine whether the November 2011 policy changes were effective in limiting the amount of open market purchases through the PPV. Determine whether the new PPV contract (effective in August 2012) will effectively limit the amount of open market purchases through the PPV.
6. Determine whether VA was initially charged the correct contract prices for purchases through the PPV. If not, determine whether the PPV later corrected the prices either independently or in response to Pharmacy Benefits Management's (PBM) price adjudications.
7. Determine whether VA's open market purchases violated procurement laws and regulations and, if so, determine to what extent such violations occurred.
8. Determine whether VA purchases complied with the Trade Agreements Act.

[1] FY 2011 is defined as October 1, 2010, through September 30, 2011.

Results

We reviewed VA open market purchases and contract purchases through the PPV during FY 2011 as well as other documents and correspondence related to the PPV program. We also conducted interviews of personnel involved in all aspects of the PPV program, from ordering pharmaceuticals to administering the PPV contract, and from managing to verifying contract prices.

We found that the amount of VA open market pharmaceutical purchases in FY 2011 was significantly less than originally estimated. This was in large part due to contract purchases erroneously appearing as open market purchases due to inconsistencies in the PPV's ordering system. Despite these system issues, we concluded that the PPV charged the correct contract prices directly or through credits and rebills. We also found that VA often purchased pharmaceuticals open market because contract products were in shortage, backordered, or out of allocation, which are problems not unique to the VA.

Also, we found that the policy changes and procedures implemented by VA in November 2011 did not preclude or prohibit open market purchasing. Instead, open market purchases were shifted from the PPV contract to other financing accounts. Furthermore, open market purchasing has continued due to lack of training for VA's Ordering Officers and the ability to circumvent procurement regulations when placing open market orders through the PPV. Because open market purchases have shifted to different financing accounts, there is less visibility and we have concerns that the new PPV contract will not be effective at limiting open market purchases.

We found that it was difficult to quantify open market purchases without conducting an in-depth review because a large number of products identified as open market purchases were actually on contract but not identified as such in the database. As a result, our review of open market purchasing trends under the new system was inconclusive.

In addition to reviewing the purchases identified in the FY 2011 data as open market, we sampled transactions identified as contract purchases. We did not find significant problems with overcharging. As with the open market products, we concluded that corrections are made over time as adjustments to the contract price are processed and entered into the PPV system.

Recommendations

We recommend that the Under Secretary for Health:

1. Require Pharmacy Benefits Management (PBM) to continue its monthly price adjudication process to include all sales transactions of both on contract and open market products through the PPV contract or other financing accounts.[2] This process, in conjunction with the National Acquisition Center (NAC), should be improved so that pricing errors are identified and resolved in a timelier manner.

2. Seek legislative changes to revise the annual Federal Ceiling Price (FCP) implementation date from January 1st to February 1st of each year to provide ample time to process the Non-Federal Average Manufacturer's Price (Non-FAMP) data.

3. Ensure that the PBM price file uploaded into the PPV's ordering system uses the contract expiration date for all FCP prices versus the December 31st expiration date of FCP prices.

4. Block the purchase of approved WAC Based Priced Generics (WBPG) if a comparable generic product is on contract.

We recommend that the Principal Executive Director for Acquisition, Logistics, and Construction:

5. Require the PPV to update its ordering system to ensure all transactions (especially rebills) for products on contract record the appropriate contract number in the database.

6. Require the NAC to award contract price changes in a timely manner to avoid backdating of price changes.

7. Determine the feasibility of creating an electronic interface to allow the price files to be updated with the vendor supplied Excel spreadsheets to eliminate the necessity for manually entering prices.

8. Seek legislative changes that would require manufacturers/dealers/resellers to offer generics on contracts.

9. Request the PPV contracting officer issue a modification to the PPV contract requiring monthly reporting of all open market purchases through the PPV contract/FastPay and open market purchases through other financing accounts.

[2] PBM's price adjudications in FY 2011 did review all sales and attempted to correct pricing issues specifically related to contract products appearing in the open market. However, after policy changes and the implementation of separate financing accounts for open market purchases, PBM is no longer reviewing the additional open market sales under the new account number.

We recommend that the Under Secretary for Health and the Principal Executive Director for Acquisition, Logistics, and Construction:

10. Require the PPV to update its ordering system interface to work with the Consolidated Mail Outpatient Pharmacy's (CMOP) system and require all facilities, including the CMOPs, to use McKesson Connect when placing orders in the future.

11. Prohibit purchasing through the PPV products sold on the FSS by manufacturers who do not participate in the PPV program. Instruct VA facilities to purchase these products directly from the FSS contractors or their authorized distributor at or below the FSS price.

12. For generic pharmaceuticals, use alternatives to long-term firm fixed-price contracts that are more consistent with commercial practices and provide an incentive to manufacturers to offer their products on contract.

13. Require the PPV to update its system to block VA Ordering Officers from placing open market orders. At a minimum, VA facilities should not be allowed to order open market products through the same web-based ordering system (McKesson Connect) used for the PPV program.

14. Provide training to Ordering Officers in allowable and unallowable procurement practices and revoke the warrant of any ordering officer found to be engaging in unallowable procurement practices.

15. Conduct a study to determine the impact the Trade Agreements Act (TAA) has in restricting access to generic pharmaceuticals and to what extent waivers or regulatory changes are necessary to ensure adequate product availability.

Under Secretary for Health and Office of Acquisition, Logistics, and Construction Comments

The Under Secretary for Health and the Principal Executive Director (PED), Office of Acquisition, Logistics, and Construction (OALC), provided their written responses to our findings and recommendations on September 24, 2012. As stated in the Under Secretary for Health's memorandum, Veterans Health Administration (VHA) will work with OALC to implement the Action Plans provided for in the PED's memorandum dated September 24, 2012.

OALC non-concurred with recommendations 4 and 9, and partially concurred with recommendation 11. The intent of recommendation 4 is to ensure that generic products on FSS contracts are procured prior to the purchase of WBPG. This would be accomplished by having the PPV block WBPG generics if an FSS product is on contract and available at sufficient quantities to fill the order. The response stated that the most frequent reason for purchasing a WBPG is contract products are out of stock, that Ordering Officers must be held accountable for their decisions at the time of ordering, and that the recommendation will cause delays in the fulfillment of orders. We noted that under the new PPV contract, WBPG are the lowest priority in the revised ordering hierarchy. However, the revised hierarchy is similar to the previous hierarchy which had open market items as the lowest priority. If a block is not in place, Ordering Officers can place an order for any product listed in the PPV ordering system regardless of the hierarchy. In addition, VA does not have a system in place to monitor compliance with the hierarchy. Contractors spend significant resources to obtain an FSS contract and comply with its provisions. Allowing the purchase of a WBPG when an FSS product is available diminishes the integrity of the FSS program. Placing WBPG at the bottom of the ordering hierarchy is a step in achieving the desired results of the recommendation; however, implementing a block as recommended is the only guaranteed way to ensure compliance and maintain the integrity of the FSS program.

Recommendation 9 requested a modification to the current PPV contract that requires the reporting of all purchases through the PPV regardless of whether the products are on contract. OALC's response is that open market purchases are not authorized through the new PPV contract. We found the response to be vague so we sought additional clarification on OALC's response from the Associate Deputy Assistant Secretary (ADAS) for National Healthcare Acquisition. The ADAS stated that although the PPV contract does not provide for monthly reporting of open market purchases, the VA can request reports of open market purchases from McKesson if necessary.

Our review determined that numerous contract purchases were reported as open market purchases because the contract number field was not populated in McKesson's database. These errors were caught through the "adjudication" process performed by PBM, reports from customers, and McKesson's credit and rebill process. If McKesson's ordering system fails to have a contract number for valid contract products and such products are ordered open market, the chances of an overcharge not being caught and corrected are significant. Without a report of open market purchases, the VA National Acquisition Center will have no way of verifying that McKesson's ordering system was corrected. In addition, for other cost recovery purposes such

as civil fraud actions brought under the provisions of a *qui tam* under the False Claims Act, we maintain that it is necessary for all VA purchases to be reported to VA. The PPV contract provides the opportunity to require such reporting.

OALC partially concurred with recommendation 11. We discussed OALC's response with the ADAS for National Healthcare Acquisition because the response appeared to have contradictory statements. The ADAS stated that all non-PPV contract items are currently locked out of the McKesson's ordering system and that VHA wants a system in place that would allow for the next day delivery of non-PPV products from those manufacturers who do not participate in the PPV program. We agree that for emergency situations the system should allow for the purchase of products for next day delivery from the PPV but only if those products cannot be obtained from the manufacturer for next day delivery. As noted in our findings, all pharmaceutical contracts include provisions for emergency delivery, which should obviate the need for ordering through the PPV. We accept the action plan for recommendation 11, as it addresses the intent of the report finding. We will continue to monitor purchases to determine compliance.

OALC fully concurred with 12 of the 15 recommendations and provided acceptable implementation plans. We will follow up on the implementation of the planned actions until they are completed.

Michael Grivnovics

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INTRODUCTION

Purpose and Objectives

The purpose of this review was to quantify the extent and determine the cause of problems associated with VA's open market purchases of pharmaceuticals through the Pharmaceutical Prime Vendor (PPV). To do this, we established eight key objectives that focused on quantifying the amount of open market purchases, determining the reasons for and cost impact of those purchases, and whether policy changes implemented in November 2011 effectively limited open market purchases. We also focused on open market purchases of products that were on contract, the extent and cause of the problem, including any monetary impact that may have resulted. Although this review focused on open market purchases of pharmaceuticals, the Office of Inspector General (OIG) performed a limited review of contract purchases of pharmaceuticals through the PPV to verify that VA was charged the appropriate contract price.

Background on PPV Program

History and Award of the PPV Contract

In July 1993, the VA Secretary made the decision to close VA's depots and endorse the system-wide implementation of PPVs. The PPV is a concept of support whereby a primary commercial distributor serves as the provider of a broad range of pharmaceuticals to VA facilities and a multitude of Other Government Agencies (OGAs). In addition to VA, other Federal government customers eligible to use VA's PPV contract are U.S. Public Health Service (PHS), Bureau of Prisons (BOP), and the Immigration and Naturalization Service (INS). Authorized State Veterans Homes (SVHs) that have sharing agreements with VA facilities also are eligible to use the contract. The use of PPVs is a common commercial business practice.

The PPV services over 750 customers in the 50 United States, the Virgin Islands, Saipan, Puerto Rico, and Manila, Philippines, for just-in-time delivery of contracted pharmaceutical products. Pricing for the majority of the pharmaceutical products distributed through the PPV are established by the Federal Supply Schedule (FSS). However, products are also priced using Blanket Purchase Agreements (BPAs), National Contracts (NCs), and other local or regional agreements. Pricing under these contracts and agreements are maintained by VA in a database that is uploaded by the PPV into the PPV's ordering system. Use of the PPV is mandatory for VA pharmacies and optional for OGAs, such as the Indian Health Service (IHS). However, manufacturers with FSS contracts are not required to sell their product to VA and OGAs through the PPV.

The PPV contract, V797P-1020, was awarded competitively to McKesson on December 31, 2003, with an effective date of April 1, 2004. The base period of performance was for 2 years with three (3) 2 year renewable options. The contract, which has been in effect continuously for the last 8 years, expired on May 9, 2012; however, a new PPV contract was recently awarded competitively to McKesson with a base period of August 10, 2012, through August 9, 2014, with

three (3) 2 year options.[3] Unless otherwise stated, all references to the PPV contract in this report relate to contract number V797P-1020 and do not refer to the contract awarded on April 11, 2012.

Administration of the PPV Contract

VA's National Acquisition Center (NAC) is aligned under the Deputy Assistant Secretary for the Office of Acquisition and Logistics. The NAC has two major divisions: FSS Service and National Contract Service (NCS). The NCS is responsible for several programs including the PPV program. The NAC PPV contracting officer's duties include awarding and administering the PPV contract, monitoring prime vendor performance, and resolving contract issues. The NCS also awards and administers competitively awarded contracts for pharmaceutical products. The FSS Service is responsible for the award and administration of FSS contracts with individual pharmaceutical manufacturers.

Veterans Health Administration's (VHA) Pharmacy Benefits Management (PBM) Services is aligned under the Deputy Under Secretary for Health for Policy and Services and is responsible for developing policies to improve the safety and efficiency of VA's medical facility inpatient and outpatient pharmacies. PBM is also responsible for determining and managing VA's formulary. In addition, PBM has responsibility annually for processing all non-Federal Average Manufacturer's Price (Non-FAMP) calculations for covered drugs as required under Section 603 of Public Law 102-585 – Veterans Healthcare Act. The Chief Procurement and Logistics Officer in VHA has responsibility for all Ordering Officers and logistics staff who place orders through the PPV.

Although the PPV contracting officer is responsible for resolving PPV price issues, PBM routinely performs pricing validations (also known as price adjudications) and provides the results of those analyses to the PPV contracting officer. PBM's business practice is to review prices for all pharmaceutical products purchased from the PPV each month, beginning 3 months after the purchase. For example, purchases made in July 2011 would be reviewed in October 2011. This delay allows sufficient time for adjustments initiated by purchasing activities or the PPV to reflect correct pricing. PBM provides the PPV contracting officer a monthly price analysis, which shows differences between amounts paid and the contract prices for specific pharmaceutical products. The PPV contracting officer then submits these price analyses to the PPV for resolution. The PPV can take up to a year to complete a monthly review submitted by VA. For example, PBM's price adjudication covering March 2011 was submitted to the PPV in September 2011, and the PPV provided final resolution at the end of March 2012. The PPV's resolution includes the final amount credited and an explanation for the amounts that are not credited. The PBM's price adjudications generally do not take into consideration pricing of products that are limited through allocation.

[3] A bridge contract (VA797P-12-C-0022) with McKesson is currently in effect from May 10, 2012, through August 9, 2012, and was awarded to McKesson using a Justification for Other Than Full and Open Competition.

Pricing of Pharmaceuticals and Other Supplies under the PPV Contract

Pricing for products purchased through the PPV contract is primarily established through FSS contracts but may also be based on local and national BPAs and NCs. If a pharmaceutical product is a covered or branded drug, then it may also be subject to a Federal Ceiling Price (FCP).[4] The FSS Service is responsible for awarding and administering FSS contracts, which includes updating FSS contract prices reported in the NAC's Contract Management System (NAC CM).[5] For most FSS price changes, the FSS contracting officer sends a copy of the modification to the Program Management and Resource Support (PMRS) Division of the FSS Service. PMRS then manually enters the price(s) into the NAC's system. However, if a product is a new award or addition, or there is a National Drug Code (NDC) [6] change, the FSS contracting officer sends the modification to PBM and it inputs the price(s) into the NAC's system instead of PMRS. Every night PBM then pulls all contract prices from the NAC CM, and a reformatted file is provided to the PPV for download, which is performed every morning. Any contract prices not in this file, such as local or regional pricing agreements, must be submitted to the PPV contracting officer for verification and then they are forwarded to the PPV to be entered into its system.

Pricing for any open market products would be based on the PPV's list price. The PPV contract defines an open market product as "any item/product/unit not under a current Federal government contract." Note that the new contract awarded to McKesson includes negotiated pricing for products that are not on FSS or other VA contract. The new contract expressly excludes the sale of open market products.

Ordering Pharmaceuticals and Other Supplies through the PPV Contract

To order pharmaceuticals and other supplies through the PPV, an eligible customer would first attempt to purchase products that were already on contract. The PPV would then charge the customer the contract price less a negative distribution fee.[7] As stated earlier, the PPV downloads a price file from PBM every morning which contains all active contract prices (except local or regional agreements), and then uploads this file into its ordering system.

Selling through the PPV is not mandatory for FSS and other pharmaceutical contractors; the contractor can elect not to participate in the PPV program. Therefore, any purchases through the

[4] The FCP is the maximum price manufacturers can charge for covered drugs to the Big 4 — VA, Department of Defense (DoD), PHS, and the Coast Guard — even if the FSS price is higher. The FCP must be at least 24 percent below the non-FAMP.

[5] The NAC's CM System is maintained and operated by the Operations and Analysis Division of Business Resource Support (BRS) at the NAC.

[6] An NDC is a unique product identifier used for drugs in the United States. It has 10 numeric digits, divided into 3-segments. The first segment, the labeler code, identifies the labeler, which is any firm that manufactures, distributes, or repackages a drug product. The second segment, the product code, identifies a specific strength, dosage form, and formulation for a particular firm. The third segment, the package code, identifies package forms and sizes.

[7] The negative distribution fee during FY 2011 was 4.9 percent for NET 15 (paid within 15 days) or 5.15 percent for FastPay sales. FastPay is an expedited payment procedure used under the PPV program, wherein payments are made to the PPV in 24 to 48 hours, in contrast to NET 15 days.

PPV from these non-participating vendors are considered open market even though contract prices exist for their products. We also found that one FSS contractor during FY 2011 had an allocation agreement in place for some of its products. The allocation agreement sets forth a limit on the amount of a product that would be allocated to VA customers per month and per year. Once VA reached this limit (usually within hours of the first day of the month), any additional purchases of these products would be at the PPV's list price not the FSS contract price. For these types of allocation purchases, the PPV has two product numbers that are internal to the PPV and are not synonymous with the products' NDC. The PPV uses these product numbers to distinguish between purchases made of the allocated units priced at the applicable contract price and those purchased above the allocation at the PPV's list price. Purchases over and above the allocated units are priced at the PPV's list price and use the second product number.

The PPV contract does allow for open market purchases at the discretion of an eligible customer (but only after the customer has complied with internal policies and all applicable procurement regulations). A customer would place an open market order through the PPV by entering in the product number or NDC and adding it to the purchase order. All products ordered (whether on contract or not) would receive the negative distribution fee.

Purchases (contract and non-contract) are typically made through McKesson Connect, a proprietary web-based ordering system, or through EconoLink. EconoLink is also a McKesson-developed proprietary order and inventory management system (client-server based); it is the predecessor to McKesson Connect. EconoLink is a client-server based software package that is loaded on computers at the customer site, whereas McKesson Connect is a web-based product that is essentially accessed via the internet but running on the PPV's servers. McKesson Connect is an "online" real-time system and tied directly into the PPV's backend systems with search screens and generic equivalent screens and displays a distribution center's product quantity (that is refreshed in real-time). During FY 2011 VA facilities used McKesson Connect and VA's seven Consolidated Mail Outpatient Pharmacies (CMOPs) used EconoLink.

If any pricing errors occur during a sales transaction, the PPV would correct the issue through a credit and rebill process. The PPV would fully credit the original invoice containing the pricing error, and then rebill with a new invoice containing the correct pricing. For example, if a customer purchased a contract product but the PPV mistakenly processed the sale as open market, the PPV would then credit the original open market purchase in full, and rebill the contract product at the contract price. The original invoice and credit would reflect that no contract number was used for pricing, but often the rebill would reflect a contract number.

Recent Policy Changes on Open Market Purchases

Prior to November 8, 2011, open market purchases through the PPV were allowable as long as customers followed all applicable procurement regulations. Any open market products were listed on the purchase order and invoiced with all contract products ordered; open market products were identified by the lack of a contract number to establish pricing. On November 8, 2011, the Deputy Under Secretary for Health for Operations and Management sent a memo

directing VHA Pharmacy Departments to immediately cease all improper purchases of open market products through the PPV. Open market products valued at $3,000 or less could be purchased using the Government purchase card; however, anything valued above $3,000 would have to be forwarded to the contracting department so that the products could be procured by a warranted contracting officer.

Around this time VA worked with the PPV to change the ordering system so that purchases of open market products did not occur under the PPV contract. The PPV set up separate financing accounts for each facility or ordering office – one for contract purchases under the PPV contract and another for open market purchases through the PPV. At a minimum, each facility or ordering office within a facility was assigned a PPV account number and an open market account number. The PPV account number was paid using the FastPay system; the open market account number was paid using a Government purchase card. If a customer wanted to purchase an open market product through the PPV, it would have to set up a separate purchase order under its open market account number. Any open market products purchased under this separate account were no longer awarded the negative distribution fee. Open market products were priced based on the PPV's list price. This new ordering process essentially segregated contract purchases from open market purchases, but did not actually prohibit or in any way limit the amount of open market purchases through the PPV. In addition, because the price was not reduced by the negative distribution fee, VA paid more for the products that it was paying before the bifurcation of open market and on contract purchases.

Overall Scope and Methodology

To address the objectives of this review, we requested and received all purchases of contract and open market products made through the PPV from October 1, 2010, through September 30, 2011. Our review focused primarily on open market pharmaceutical purchases by VA customers. We did not review PPV sales to non-VA customers, and we did not review in detail any purchases of medical/surgical supplies.

We also interviewed several key personnel at the NAC and PBM responsible for the award and administration the PPV contract, as well as conducted phone calls/correspondence with McKesson personnel. Additional interviews of CMOP personnel stationed in Hines, IL, and Leavenworth, KS, as well as pharmacy staff responsible for procuring supplies for the VA Medical Centers (VAMCs) in San Francisco, CA, and Washington, DC, were conducted to gain a better understanding of how the PPV program operates at the ordering level.

We also reviewed:

- Additional purchase data (PPV and open market) for the months of December 2011 and January 2012.
- PPV contract number V797P-1020 and all subsequent modifications, as well as the new PPV contract number VA797P-12-D-0001 awarded on April 11, 2012.
- Monthly reports generated by the PPV as required in the contract.

- Contract price files in effect during FY 2011 as provided by PBM (these price files are the same ones uploaded daily into the PPV's ordering system).
- Price adjudications performed by PBM for FY 2011 and the resulting price corrections by the PPV.
- Weekly notes from FY 2011 released by the NAC to purchasers detailing drug shortages and open market products.
- Allocation agreements established between certain FSS contractors and the NAC.
- Documents submitted by customers related to product pricing errors and/or issues with whether products were on contract.

RESULTS AND RECOMMENDATIONS

OBJECTIVE 1: Determine total VA purchases of open market products through the PPV during fiscal year (FY) 2011.[8] Of the open market purchases, determine the total pharmaceuticals and medical/surgical supplies purchased.

Scope

We reviewed all FY 2011 PPV purchase data to determine the amount VA spent on open market purchases. The data was separated by VA and non-VA customers. The VA data was further separated into contract and non-contract (also known as open market) purchase transactions based on whether a contract number was populated in the appropriate data field. The key to identifying an open market transaction is whether a valid FSS or other contract number appeared in the data. The VA open market purchases were further separated to determine the amounts spent specifically on pharmaceuticals and medical/surgical supplies. Although medical/surgical products are not considered pharmaceuticals, the PPV contract allows for purchases of certain medical/surgical products that are for outpatient dispensing only such as gloves and syringes.

After further review of VA's FY 2011 open market pharmaceutical purchases through the PPV, we determined that many transactions were contract purchases even though the data did not include a contract number. Therefore, we attempted to reconcile those products incorrectly categorized as open market by further extracting any "open market" products that were actually on contract as represented in PBM's price files.

Results

Difficulty in Quantifying Total Actual Dollars in Open Market Purchases

We determined that of the $4.3 billion in overall reported VA purchases through the PPV in FY 2011, approximately $290.1 million were identified as open market purchases because there was no contract number identified in the data. Therefore, approximately 6.7 percent of overall reported VA purchases through the PPV appeared to be open market. Of the $290.1 million in open market purchases, $7.4 million were for medical/surgical products leaving $282.7 million for pharmaceutical products.

However, as stated above, we determined that the $282.7 million identified as open market pharmaceutical purchases actually included a large number of transactions that were contract products that did not have a contract number. After comparing the $282.7 million in open market purchases to PBM's FY 2011 price files of contract products, we determined that an estimated $145.8 million[9] of the purchases were actually contract products for which no contract

[8] FY 2011 is defined as October 1, 2010, through September 30, 2011.
[9] This was only an estimate as it included any open market sales of products that (a) were out of allocation and (b) may have been on contract for only part of FY 2011.

number was identified in the data. Objective 2 provides a more detailed analysis of approximately $63.3 million in VA contract purchases identified as open market.

Actual open market purchases were 3.2 percent of the overall reported VA purchases through the PPV. Therefore, an estimated $136.9 million of the $282.7 million in purchases were open market or non-contract purchases, which is less than the originally computed 6.7 percent. We also found that the $136.9 million included purchases of products that were on contract but the manufacturer declined to participate in the PPV program. As previously stated, although these vendors have products on FSS contracts at or below the FCP, purchases made by VA through the PPV are considered open market and the PPV is not required to honor the FSS prices. Objectives 3 and 4 provide a more detailed review of VA's actual open market pharmaceutical purchases.

We concluded that open market purchases through the PPV were significantly less than originally estimated due to a large amount of transactions for contract products not having a contract number. After additional analysis, we determined that many of the transactions (making up the $145.8 million) that were missing a contract number were rebills.[10] The PPV told us that rebills should have had a contract number listed if it was a contract sale. The PPV further stated that the issue of blank contract numbers is a consistent occurrence and appears to be a software issue. They are continuing to research the problem and stated they will fix their ordering system once the problem is isolated. Because a significant number of rebills were showing up as open market purchases, it was difficult to quantify the actual dollars spent on open market products. Therefore, the estimated $136.9 million of actual open market purchases is our best approximation based on inconsistencies identified with the data.

Recommendations

We recommend that the Under Secretary for Health:

> Require PBM to continue its monthly price adjudication process to include all sales transactions of both on contract and open market products through the PPV contract or other financing accounts.[11] This process, in conjunction with the NAC, should be improved so that pricing errors are identified and resolved in a timelier manner.

We recommend that the Principal Executive Director for Acquisition, Logistics, and Construction:

> Require the PPV to update its ordering system to ensure all transactions (especially rebills) for products on contract record the appropriate contract number in the database.

[10] A rebill is a new invoice or sale as a result of a price correction to the original invoice. The price difference is not rebilled, but rather an entirely new invoice is created and the original invoice is credited in full.

[11] PBM's price adjudications in FY 2011 did review all sales and attempted to correct pricing issues specifically related to contract products appearing in the open market. However, after policy changes and the implementation of separate financing accounts for open market purchases, PBM is no longer reviewing the additional open market sales under the new account number.

OBJECTIVE 2: Determine total VA purchases of open market products of on contract pharmaceuticals. Determine why on contract pharmaceutical products were purchased open market. Ascertain the monetary impact, if any, of purchasing on contract pharmaceutical products open market.

Scope

To answer the objectives stated, we conducted a detailed analysis of the $282.7 million in VA pharmaceutical purchases identified as open market in FY 2011 and determined the amount that represented contract products. Although we identified $145.8 of the $282.7 million of the purchases were contract products, we included them in our review to determine why these purchases were identified as open market (or without a contract number listed) and whether there was a monetary impact when contract products were purchased as open market.

We selected a sample of 100 pharmaceutical products representing most of the largest selling products VA purchased that were identified as open market that represented 38.1 percent of total purchases identified as open market ($107,651,341 ÷ $282,764,185). We then identified how many of the 100 pharmaceutical products were actually on contract at the time of purchase by matching the NDCs to PBM's FY 2011 price files.

If a pharmaceutical product was found to be on contract, we determined whether the PPV charged the correct contract price or a higher price (open market price). For this analysis, we used PBM's FY 2011 price files and found the lowest contract price in effect at the time of purchase (as multiple contract prices may have existed on FSS, NCs, or national BPAs). We do note that we did not have visibility of any local or regional pricing agreements that may have existed to determine whether there were any overcharges related to these agreements. If the PPV charged the correct contract price, we proceeded to determine why the product was identified as an open market purchase. If the PPV charged a price higher than the contract price, we calculated the potential overcharges. Finally, we reviewed additional purchase data to determine whether the potential overcharges were corrected at a later date or if there was a reasonable explanation for the open market purchase.

Results

Significant Amount of Open Market Purchases of Contract Products but no Monetary Impact as a Result

We found that 43 of the 100 sampled pharmaceutical products identified as open market were actually on contract. This amounted to approximately $63.3 million in contract pharmaceutical purchases identified as open market or 59 percent of the total purchases sampled.

- Twenty-nine of the 43 products (or approximately $35.7 million) were sold at the correct contract prices even though they were incorrectly identified as open market by the PPV. As discussed earlier, many of the transactions were rebills that failed to identify a contract number in the data.

- For the remaining 14 products (or approximately $27.6 million), we determined that VA was charged open market prices, not the Government contract prices. These 14 products initially had potential overcharges of $9.4 million. However, after further review we determined that $5.5 million of the $9.4 million (or 7 of the 14 products) were related to the product being out of allocation. These were not actual overcharges since products out of allocation were supposed to be priced open market once VA's allocation ran out.

- The remaining $3.8 million (or 7 of the 14 products) in potential overcharges were related to backdating or late notification of FSS pricing ($3.5 million), or simply incorrect pricing ($273,471) by the PPV. However, we reconciled most of these potential overcharges with credits issued by the PPV at a later date. The remaining potential overcharges are currently under review by the PPV because PBM identified the overcharges in its price adjudications but the PPV has yet to issue a final resolution.

Although it appeared that there were potential overcharges of $9.4 million for the 14 contract products identified as open market, there was no significant monetary impact since a legitimate reason existed for the open market purchase (product out of allocation) or explained the incorrect pricing and subsequent adjustment (backdating or late notification of FSS prices; discrepancy/incorrect pricing).

Possible Reasons for Contract Pricing Errors

We concluded that actual price errors were usually the result of delays in contract pricing changes – either backdating or late notification of FSS prices. One major cause of the backdating is the annual calculation of FCPs. All vendors are required to submit their Non-FAMP data to PBM by November 15th for a January 1st implementation. Due to the tight time frame to submit the Non-FAMP data and to calculate annual FCPs, the January 1st implementation date is missed. Also, it is not uncommon for vendors to have numerous technical questions regarding their annual submissions that can further delay the process. In addition, historically the PBM price file contained prices for covered drugs with an end date of December 31st. This caused the product to drop off the NAC CM pricing file downloaded by the PPV if the new annual FCP price was not implemented by January 1st resulting in the product being considered non-contract at the time of purchase.

Another area of concern is the process used to enter pharmaceutical prices into the NAC CM. As discussed in the Background section, the process for updating most pricing actions consists of manually entering prices into the NAC CM. When seeking a new FSS contract, adding products, or modifying prices, all FSS vendors complete an Excel spreadsheet which includes all the data necessary to add prices to the NAC CM. However, the pricing database cannot accept the data from the Excel spreadsheets, which makes it necessary to add prices manually.

We also determined that some of the pricing errors may be a result of the CMOPs using a different purchasing system than VA facilities. As stated earlier, CMOPs typically used EconoLink to submit purchase orders to the PPV, whereas VA facilities used the web-based

ordering system McKesson Connect. EconoLink is outdated and does not always reflect the most accurate pricing if pricing updates are not completed timely, which may be contributing to problems with data inaccuracies. McKesson stated that EconoLink does have the ability to look-up and check availability of products but, because it is a client-server based system, it may not always be connected and updating the data (contract prices) as quickly as it does with McKesson Connect. In discussions with CMOP personnel, we learned of one instance where products appeared on contract in one ordering screen, but open market in another screen or final invoice (or vice versa). However, after investigating this issue further, we determined that the product had actually fallen off contract but EconoLink had not been updated quickly enough to reflect that on the ordering screen. Another pricing discrepancy from a CMOP showed different prices between McKesson Connect and EconoLink. McKesson provided documentation to show that the correct contract price was billed but that for some reason in one system the product was shown as open market only.

We concluded that because EconoLink is a client-server based system, it is not a reliable method for ordering when compared to McKesson Connect. Pricing discrepancies or errors are more likely to occur in EconoLink because it may not always reflect the most updated data.

Contract Products Purchased from Non-Participating Vendors

In addition to the 43 products (out of the sample of 100 items identified as open market purchases) that we determined to be on contract, we found that 9 products (or approximately $8.6 million in purchases) were on FSS contracts but purchases through the PPV by VA customers were open market because the FSS vendors do not participate in the PPV program. The nine products were all covered or branded drugs on FSS contracts at the FCP, which is the highest price VA can pay when purchasing from the manufacturer or the manufacturer's authorized distributor. Because the FSS contractor elected not to participate in the PPV program, the PPV is not required to offer the FSS price. We identified overpayments of approximately $4.8 million because VA customers purchased pharmaceuticals open market through the PPV when the vendor did not participate in the PPV program. The Ordering Officers should have purchased the products directly from the vendor or authorized distributor. Purchasing information is included on the NAC's website.

We were told that the purchases may have been made through the PPV because the order was less than the minimum available through the FSS contract. To verify this, we reviewed a select number of FSS contracts of vendors that do not participate in the PPV program but did not find any significant minimum order limitations which would have required a VA customer to purchase products through the PPV instead of directly from the vendor. We were also told that these purchases may have been made because they were needed immediately but we found that all of the contracts included procedures for emergency purchases. We also noted that not all purchases consisted of one or two units but many appeared to be a consistent purchase that could be planned for with a purchase directly from the vendor. This would have resulted in VA being charged the FCP price instead of an open market price through the PPV. We initially identified this problem through our post-award reviews and raised this issue to VA in 2007 and again in 2011. In 2007, we were told that the PPV purchasing system was changed to block purchasers

from buying these products through the PPV; however, in 2011 when we found that the problem had not been resolved we learned that at VA's request, the system allows the purchaser to override the block.

Recommendations

We recommend that the Under Secretary for Health:

Seek legislative changes to revise the annual FCP implementation from January 1st to February 1st of each year to provide ample time to process the Non-FAMP data.

Ensure that the PBM price file uploaded into the PPV's ordering system uses the contract expiration date for all FCPs prices versus the December 31st expiration date of FCP prices.

We recommend that the Principal Executive Director for Acquisition, Logistics, and Construction:

Require the NAC to award contract price changes in a timely manner to avoid backdating of price changes.

Determine the feasibility of creating an electronic interface to allow the price files to be updated with the vendor supplied Excel spreadsheets to eliminate most of necessity for the manual entry of prices.

We recommend that the Under Secretary for Health and the Principal Executive Director for Acquisition, Logistics, and Construction:

Require the PPV to update its ordering system interface to work with the CMOPs' system and require all facilities, including the CMOPs, to use McKesson Connect when placing orders in the future.

Prohibit purchasing through the PPV products sold on the FSS by manufacturers who do not participate in the PPV program. Instruct VA facilities to purchase these products directly from the FSS contractors or their authorized distributor at or below the FSS price.

OBJECTIVE 3: Determine why non-contract pharmaceuticals were purchased open market. Determine if comparable pharmaceuticals were on contract and/or available for any non-contract open market purchases and, if so, determine why the non-contract products were purchased instead of on contract products.

Scope

Using the same sample of 100 products reviewed under Objective 2, we quantified how many of the 100 pharmaceutical products were not on contract at the time of purchase by matching the NDCs to PBM's FY 2011 price files. After identifying the products that were actually on contract at the time of sale (by matching the NDC to PBM's master price file), we reviewed the remaining non-contract products to determine whether comparable on contract products existed. We then searched PBM's FY 2011 price files to identify products with similar descriptions using the products' generic or trade names, as well as the strength, form, and package size. If we found that a comparable product was on contract, we determined whether the product was available at the time of the open market purchase. We relied on the NAC's weekly open market notes and drug shortage notes for the additional information needed to determine the availability of contract products at the time of purchase. Finally, if the contract product was available, we determined why the open market product was purchased instead of the contract product.

We also reviewed a Hotline Complaint regarding the purchase of open market products. The complainant provided six examples of open market purchases where the open market price was lower than the FSS contract price. The complaint identifies three areas of concern: 1) limiting open market purchases will increase pharmaceutical expenses, 2) at times there is a necessity to purchase open market, and 3) the new process is burdensome.

Results

Reasons for Open Market Purchases of Non-Contract Products

We found that 48 of the 100 products in our sample were not on contract for all or part of FY 2011 or were not sold at contract prices. This amounted to approximately $35.7 million in non-contract pharmaceutical purchases identified as open market (or about 33 percent of our total sampled purchases). Typically, the reason for the open market purchase of these products fell into one or more of the following categories:

- Shortages or backorders of the equivalent contract product(s).
- Allocation amounts for products on contract were reached.
- The vendor did not want to put the product on a Government contract and/or it was the only (sole) source for the product.
- The product did not comply with the Trade Agreements Act (TAA) as it was manufactured in a non-designated country.
- The branded version was no longer on contract or it was discontinued, so only open market generic versions were available.

- There was an FSS contracting issue (such as the product fell off contract or the NDC/package size changed).

The two most common reasons were that: (1) the contract equivalent(s) were not available because of a shortage, backordered, or out of allocation, and (2) the open market product was the only product available. We have found through this review and our post-award reviews that a growing number of products are not on contract because there is no requirement that manufacturers offer generic drugs on FSS contracts and an increasing number of products are not compliant with the TAA and cannot be offered on the FSS or other contracts. Also, as previously stated, we found another nine sample products were sold open market because the vendor did not participate in the PPV program.

In regards to the Hotline Complaint, our review of the six products showed that the open market prices were less expensive and that at times open market purchases were necessary due to product shortages or backorder issues. We noted for three of the products that the only apparent reason for the open market purchases were lower prices because we found that the contract products were available. From this complaint we also learned that at times due to shortages, the PPV will limit the availability of a product across all customers so any one customer cannot purchase the entire available product.

Comparable Contract Products Usually Unavailable or Costly

For 15 of the 48 products (or approximately $9.1 million) we found a comparable product on contract. Furthermore, the contract price was lower for 12 of the 15 products ($7.6 million). For these 12 products, if VA customers had purchased the comparable contract product instead of the open market version, the potential cost savings totaled $5.3 million. However, we also determined that many of the comparable contract products were not available at the time due to manufacturer shortages or backorder issues. After taking this into account, we determined that VA customers overpaid approximately $904,400.

The contract price for the remaining 3 of the 15 products ($1.5 million) was actually higher than the price for the open market products. By purchasing open market, VA customers saved approximately $535,674. In accordance with VA policy, the ordering officer should have purchased products that were on a NC or an FSS contract. We reviewed several of the instances where the open market products were purchased at lower prices than the equivalent contract products and found that this was due to the fact that generics are less expensive than the branded drugs on contract, and as stated earlier, manufacturers are not required to put generics on contract.

For 33 of 48 products (or approximately $26.6 million) we could not determine with any degree of certainty whether comparable products were on FSS (based on generic description and trade information) contracts.

We concluded that open market purchases were often necessitated by the growing number of product shortages and backorder issues with manufacturers, as well as the growing number of

generic products that vendors are not required to offer on contract or cannot offer because the product is not compliant with the TAA.

Recommendations

We recommend that the Principal Executive Director for Acquisition, Logistics, and Construction:

> Seek legislative changes that would require manufacturers/dealers/resellers to offer generics on contract.

We recommend that the Under Secretary for Health and the Principal Executive Director for Acquisition, Logistics, and Construction:

> For generic pharmaceuticals, use alternatives to long-term firm fixed-price contracts that are more consistent with commercial practices and provide an incentive to manufacturers to offer their products on contract.

OBJECTIVE 4: Identify patterns and trends in VA's open market pharmaceutical purchases.

Scope

We reviewed several elements, including, but not limited to, the top selling NDCs and vendors, as well as the top VA facilities purchasing open market, and the top VA drug classes. However, as noted in Objective 1, it was difficult to identify true VA open market purchases due to the large amount of products that were actually on contract. We attempted to segregate non-contract products from contract products found in VA's open market pharmaceutical purchases and estimated that approximately $136.9 million were truly open market purchases.

Results

We could not identify open market purchasing trends due to the large number of the products that were actually on contract.

OBJECTIVE 5: Determine whether there were any controls in place to prevent VA open market purchases through the PPV and identify such purchases in a more timely and thorough manner. Determine whether the November 2011 policy changes were effective in limiting the amount of open market purchases through the PPV. Determine whether the new PPV contract (effective in August 2012) will effectively limit the amount of open market purchases through the PPV.

Scope

To determine whether adequate oversight mechanisms were in place to prevent open market purchases in a more timely and thorough manner, we conducted interviews in person and via telephone of NAC, PBM, CMOP, and PPV personnel to understand any possible areas where there were a lack of controls. By understanding the ordering process at the facility level, and then how issues were communicated to higher levels at the NAC and PBM, we could determine what controls were in place (or lack thereof) to prevent open market purchases that occurred during FY 2011.

To determine whether recent policy changes in November 2011 effectively limited the amount of open market purchases through the PPV, we compared PPV purchase data from September 2011 to January 2012. In September 2011, purchase data for all transactions through the PPV fell under a single financing account number; open market purchases could be identified by the lack of a contract number. On November 8, 2011, VA issued a memo stating that all improper purchases of open market products through the PPV had to cease immediately. Open market purchases if under $3,000 were being placed under the FastPay account when they should have been placed using a Government purchase card. To ensure segregation of orders with contract products versus open market products, VA began using separate financing account numbers. So in December 2011 and January 2012, sales data fell under two different account numbers – contract purchases went through a PPV/FastPay account number, and open market purchases went through an open market account number. We focused primarily on any open market purchases (no contract number) that fell under the PPV account number, but we also reviewed the purchases under the open market account. Finally, we compared our findings to VA's reported decrease in open market purchases to 0.4 percent,[12] as we wanted to verify this statement.

We also reviewed the new PPV contract awarded to McKesson in April 2012, with an anticipated effective date of August 10, 2012, to determine whether the new PPV contract contained better oversight mechanisms to limit open market purchases.

[12] This decrease was reported during the February 1, 2012, hearing of the House Committee on Veterans' Affairs, entitled "Examining VA's Pharmaceutical Prime Vendor Contract." VA stated that it had reduced open market purchases to 0.4 percent in December 2011 after implementing new policy changes.

Results

No Effect on Total Open Market Purchases after Policy Changes

In our interviews with Ordering Officers at CMOPs and VA facilities, we found that ordering open market products after the policy changes was still quite easy. Although the PPV had changed the ordering screen so that open market products were not viewable when ordering contract products, a simple change in account number using a drop-down feature in McKesson Connect still allowed VA facilities to order contract products and open market products. Switching account numbers was now an additional step Ordering Officers had to take to order open market products, but the ease of ordering and convenience of the PPV's web-based system still allowed for open market purchases and did not appear to necessarily discourage these purchases.

We found that in September 2011, VA's total pharmaceutical purchases through the PPV were approximately $482.1 million. This could be further broken down into contract purchases (based on a listed contract number) of $427.5 million and open market purchases (based on no contract number) of $54.6 million. However, we found that a majority of the open market purchases were actually products that were on contract. After taking into account the contract products that appeared to be open market because there was no contract number, we determined that the actual open market purchases totaled approximately $18.9 million (instead of $54.6 million). This meant approximately 3.9 percent of total VA pharmaceuticals purchases through the PPV were open market.

We then found that in December 2011, total VA pharmaceutical purchases through the PPV were approximately $362.7 million. This included purchases under both the PPV account number and the open market account number. However, when VA calculated its open market purchases of 0.4 percent, it only reviewed purchases under the PPV/FastPay account number. We found that total VA pharmaceutical purchases under the PPV account number were $353.9 million, with $348.9 million in contract purchases and $5.0 million in open market purchases. However, some of the $5.0 million in open market purchases were actually contract products. So, actual open market purchases were closer to $4.7 million or about 1.3 percent of total VA pharmaceuticals purchases under the PPV account. Therefore, although open market purchases appear to have decreased from September 2011 to December 2011 from 3.9 percent to 1.3 percent, we did not find that open market PPV purchases decreased to 0.4 percent as VA claimed.

Furthermore, we found that there was an additional $7.4 million in open market purchases under the open market account number. Although these purchases were not made through the PPV contract, they were still made through the PPV. By combining the open market purchases under the PPV account number and the open market account number, we identified a total of $12.1 million in open market purchases or 3.3 percent of the total VA pharmaceuticals purchases through the PPV. Purchasing products from the PPV through different account numbers gives the appearance that open market purchases through the PPV contract decreased as a result of policy changes. However, in reality the amount of open market purchases did not change significantly as claimed (3.9 percent in September 2011, to 3.3 percent in December 2011, versus

the 0.4 percent reported). The purchases just shifted to a different financing account. After reviewing January 2012 purchase data we still found that open market purchases totaled $7.9 million (or 2.1 percent); and $16.0 million (or 4.1 percent) when combining open market purchases under both account numbers.

We concluded that the procedures implemented in November 2011 did not preclude, prohibit, or significantly reduce open market purchasing. Instead, open market purchases were shifted from the PPV/FastPay account to other financing accounts where they were less visible.

Inadequate Purchasing Controls in the PPV's Ordering System

We found that open market purchases were still occurring because Ordering Officers could circumvent procurement regulations and the PPV contract by placing open market orders with the PPV. There were several common practices utilized to accomplish this. First, an ordering officer could add a non-contract product back into the PPV/FastPay account if he/she knew the PPV's product number. Second, an ordering officer could scan the inventory off the shelves and all products (whether contract or non-contract) would get uploaded into the PPV's ordering system. The purchase order would have to be modified by the ordering officer in order to remove the non-contract products, which may or may not have been done. Third, an ordering officer could order directly from a vendor for a drop shipment and then give the vendor the PPV/FastPay account number. If this account number is used, then an invoice will be generated under the PPV contract. To avoid an accidental billing like this, the ordering officer should use either the open market account number, purchase card, or have the local acquisition office procure the non-contract product(s).

These workarounds were highlighted in a May 18, 2012, memo issued by the PPV contracting officer to PPV Ordering Officers and stated that the ordering officer has at least three opportunities to remove any non-contract products from a purchase. This memo was attached to a May 22, 2012, memo to all Network Directors, Medical Center Directors, and Designated PPV Contract Ordering Officers from the Under Secretary for Health and the Principal Executive Director, Office of Acquisition, Logistics, and Construction. The May 22, 2012, memo stated that these preventable practices must be completely and immediately eliminated.

We concluded that open market purchases continued through the PPV contract despite policy changes, and that the main reason for the continuation was due to lack of effective controls. VA Ordering Officers had several methods of circumventing the system and still placed open market orders under the PPV contract.

Potential Issues with New PPV Contract and WAC Based Priced Generics (WBPG)

We also reviewed the changes made to the new PPV contract to determine if such changes will preclude open market purchases and if prices paid for products previously classified as open market will be fair and reasonable. The new PPV contract states non-contract (open market) products are excluded from the PPV contract and Ordering Officers are prohibited from buying open market products through the PPV contract. Generic products that are not on contract and

have a published Wholesale Acquisition Cost (WAC), are approved by the Food and Drug Administration, and are compliant with the TAA, can now be purchased through the PPV contract at a price negotiated prior to award. These products are known as WBPG. For the most part, open market purchases should decrease significantly with the availability of WBPG. However, open market purchases can still occur by buying the products via a different financing account. Such purchases are not considered a PPV contract purchase because they are not processed through the PPV account. Also, McKesson stated that it currently provides reports to the NAC of open market purchases for those products purchased through the PPV account but is not providing reports of open market purchases through non-PPV accounts. As such, these purchases are not visible to VA.

We are concerned that FSS vendors who sell generic products may remove their products from their FSS contracts and have them sold by the PPV as WBPG. The FSS will no longer receive a discount off the FSS vendor's list price but will pay the listed WAC price less a discount equal to the awarded distribution fee. We believe this could lead to an increase in pharmaceutical prices. Based on our experience conducting pre-award reviews of FSS proposals, we have concerns whether the negotiated PPV price for these generic products is fair and reasonable. The use of WBPG was supposed to be a short term solution to decrease open market purchasing; however, we have not seen any effort to develop a long term solution.

If manufacturers do not want to put generics on FSS, VA needs to engage in the process of entering into winner-take-all contracts with manufacturers through competition. Also, we have recommended that VA use shorter term firm fixed-price contracts, similar to those used by commercial customers, to ensure competition and competitive pricing. Using WBPG assumes that the TAA will not be an issue for the PPV in complying with the new PPV contract requirements. VA needs to consider whether a waiver is appropriate to encourage vendors to offer products on the FSS or through a competitively awarded contract.

The negotiated PPV price for WBPG is equal to the WAC less the negative distribution fee. However, under the terms and conditions of the contract, this discount is instead of, not in addition to, the negative distribution fee. In reality, VA will be paying WAC to purchase these products through the PPV contract. We have two examples that highlight lack of price savings by having WBPG purchased at WAC. First, we reviewed all of the nine FSS pharmaceutical offers received in the last 18 months that included generic products. The number of products per offer ranged from 2 to 643 and the discounts offered ranged from 5 to 67.66 percent off WAC. We also received unsolicited information from a small "full-line" wholesaler that included a schedule that, based on recent VA open market purchases through said wholesaler, shows that VA achieved a 43 percent price reduction from the manufacturers' WAC. These two examples highlight the potential pitfalls of relying on WBPG. While WBPG represents a contract price, and thus reduces open market purchases, it is not necessarily a fair and reasonable price.

We also noted in a May 3, 2012, Request for Ratification of Unauthorized Commitments, that despite policy changes, open market purchases through the PPV contract have continued. On May 3, 2012, the VA Assistant Chief Deputy Under Secretary for Health for Operations and Management sent a memo to the Head of VA Contracting Activity requesting the ratification of

unauthorized commitments totaling over 3,000 transactions. These unauthorized commitments occurred between January 1, 2012, and February 29, 2012, and were paid under the FastPay system. The request concluded that the prices paid for the open market products were deemed fair and reasonable because on average the prices charged by the PPV were 6.2 percent above WAC. The memo stated that most of the purchases were a result of technology and training issues, as VA staff did not recognize that some open market orders were being forwarded to the PPV combined with contract products that were properly ordered. VA stated that it has since put several controls in place, but continued monitoring in the next few months is needed to determine whether the controls have been effective in reducing open market purchases in the FastPay Accounts.

We take exception to the statement that 6.2 percent above WAC is fair and reasonable as evidence by our pre-award reviews of proposals in which the vendors are offering significant discounts off WAC, not prices above WAC. Also, the VA is only monitoring open market purchases through the PPV contract utilizing FastPay procedures. There are still open market purchases through other financing accounts other than FastPay that need to be monitored and possibly ratified.

Recommendations

We recommend that the Under Secretary for Health:

Block the purchase of approved WBPG if a comparable generic product is on contract.

We recommend that the Under Secretary for Health and the Principal Executive Director for Acquisition, Logistics, and Construction:

Require the PPV to update its system to block VA Ordering Officers from placing open market orders. At a minimum, VA facilities should not be allowed to order open market products through the same web-based ordering system (McKesson Connect) used for the PPV program.

Provide training to Ordering Officers in allowable and unallowable procurement practices and revoke the warrant of any ordering officer found to be engaging in unallowable procurement practices.

Conduct a study to determine the impact TAA has in restricting access to generic pharmaceuticals and to what extent waivers or regulatory changes are necessary to ensure adequate product availability.

OBJECTIVE 6: Determine whether VA was initially charged the correct contract prices for purchases through the PPV. If not, determine whether the PPV later corrected the prices either independently or in response to PBM's price adjudications.

Scope

We performed a limited review of VA's contract pharmaceutical purchases through the PPV to determine whether the PPV was pricing products in accordance with the contract. If a contract number was populated, then this was considered a contract sale and subject to the pricing terms and conditions in the PPV contract.

For this question we reviewed purchases for a sample of 20 pharmaceuticals products on contract (purchases representing the largest dollar values) as well as a random sample of an additional 10 pharmaceutical products. We compared the price paid less the negative distribution fee to the contract price shown in PBM's FY 2011 price files and calculated the potential overcharges. We then reviewed in detail PBM's monthly price adjudications covering FY 2011 and the final resolutions issued by the PPV. This was to determine whether PBM's price adjudications were effective at identifying potential overcharges, and to what extent VA was able to recoup those overcharges it found in the process. PBM had completed all of FY 2011's price adjudications; however, the PPV had only completed its price reviews through March 2011. Our findings on contract pricing corrections are based on the first 6 months of FY 2011 because we only received completed PPV audits through March 2011. We also reviewed additional purchase data after FY 2011 to determine whether the potential overcharges had already been corrected through the credit/rebill process, or a reasonable explanation existed for the higher priced sale.

Results

Accurate Pricing of Contract Purchases by the PPV

Our sample of 20 pharmaceutical products represented 21.1 percent (or $883 million) of total contract purchases ($4.3 billion) through the PPV. For the 20 sample products, we found potential contract overcharges of $502,871 or about 0.06 percent of the total purchases. A majority of these overcharges ($410,375) occurred during a 1 week period in September 2011 and were related to a single NDC; however, these overcharges were corrected and credited by the PPV in October 2011, which reduced the total potential overcharges to $92,496. Our random sample of 10 pharmaceutical products totaled $2.3 million and we found no overcharges on any of the products. Based on our sample of 20 high dollar items and random sample of 10 items, we did not find significant problems with overcharging. As with the open market products, corrections were made over time as adjustments to the contract price were processed and entered into the PPV ordering system. We concluded that PPV prices were generally correct based on contract prices at the time.

Accuracy and Timeliness in Identifying and Resolving Price Discrepancies

Although the average percent in potential overcharges was minor when compared to total PPV contract purchases, we still evaluated whether price discrepancies were identified by VA and resolved in an accurate and timely manner. After identifying potential overcharges on PPV contract purchases, we reviewed PBM's monthly price adjudications to determine whether PBM documented the same errors. We found that PBM identified approximately $34,549 of the $92,496 in potential overcharges we calculated. The rest of the overcharges were not included in PBM's price adjudications for FY 2011, and we did not find any credits issued by the PPV during FY 2011 for these overcharges.

In general, we found that PBM identified an average of $1.2 million per month in potential overcharges, and in response, the PPV typically credited about $591,000 per month. Most of the credits issued by the PPV were a result of the backdating of FSS contracts, and only a small amount was a result of a PPV pricing error. The major reason for the difference in the amount identified as overcharges and the amount the PPV credited was due to product allocations. These products were purchased at a contract price until VA's allocation limit was reached, and then were sold at an open market price. PBM's price adjudications did not differentiate between the products sold at the contract price and those sold at the open market price after the allocation was exceeded. In essence, PBM identified potential overcharges when none existed. These products have only one NDC which is used by PBM to identify overcharges. The PPV uses two internal product numbers to differentiate between a contract price and an open market price based on the allocation limits. The other reason for this difference was the PPV crediting VA for the price errors on its own initiative. On average during FY 2011, McKesson credited approximately $7.1 million per month. We could not determine whether this was due to individual VA facilities notifying the PPV of price errors or the PPV finding and correcting errors on its own.

It did appear that the PPV used significant time and resources to complete its reviews of PBM's price adjudications; however, it only finalized each PBM review once all issues had been resolved. As individual transactions were resolved, they were immediately processed by the PPV. The PPV stated that some delays in resolution occurred because they had to go back to the supplier to ensure the contract price would be honored. The PPV has one full-time equivalent employee dedicated to resolving PBM's price adjudications. We concluded that the PPV accurately addressed the potential overcharges identified by PBM, although not always in a timely manner. The timeliness of resolving price discrepancies is also discussed in the OIG report *Review of the Controls for the Pharmaceutical Prime Vendor Fast Pay System* (Report No. 12-01008-185, May 17, 2012).

Recommendation

We recommend that the Principal Executive Director for Acquisition, Logistics, and Construction:

Request the PPV contracting officer issue a modification to the PPV contract requiring monthly reporting of all open market purchases through the PPV contract/FastPay and open market purchases through other financing accounts.

OBJECTIVE 7: Determine whether VA's open market purchases violate procurement laws and regulations and, if so, to what extent such violations occurred.

In testimony before the House Committee on Veterans' Affairs, VA acknowledged that procurement laws and regulations were violated by open market purchases through the PPV contract and that this practice has been in existence since the original PPV contract awarded in 1993. VA has stated that it is actively retraining personnel in procurement regulations and practices.

A May 18, 2012, memo issued by the PPV contracting officer to PPV Ordering Officers noted that VHA has self-reported in excess of 8,000 unauthorized commitments using the PPV contract during the period of November 8, 2011, through March 2012, and highlighted four common workarounds utilized by Ordering Officers to order open market products through the PPV contract. This memo was attached to the May 22, 2012, memo to all Network Directors, Medical Center Directors, and Designated PPV Contract Ordering Officers from the Under Secretary for Health and the Principal Executive Director, Office of Acquisition, Logistics and Construction. The May 22, 2012, memo stated that these preventable practices must be completely and immediately eliminated.

As previously stated under Objective 5, open market purchases should decrease under the new PPV contract with the advent of WBPG pricing. We also noted that open market purchases will still continue under financing accounts other than Fast Pay. In addition, the PPV stated the new PPV contract does not require the reporting of open market purchases through the PPV contract or through other financing accounts. Currently the PPV is providing open market purchasing reports of purchases through the PPV contract.

In order to properly monitor open market purchasing, VA needs to require the PPV to submit monthly reports showing open market purchases through the PPV contract and those using other financing accounts as outlined in Objective 5. This will provide the visibility needed to identify those items that were erroneously identified as open market when the items were, in fact, on contract and to make the necessary price adjustments.

OBJECTIVE 8: Determine whether VA purchases complied with the Trade Agreements Act.

Lot numbers relating to the products purchased are required to determine whether the products were TAA compliant. Lot numbers associated with open market purchases and contract purchases through the PPV contract were not readily available and therefore compliance testing with the TAA could not be completed. However, based on our review of the purchase transactions, we determined that the dollar values for the open market purchases were under the statutory threshold for compliance with the TAA, therefore there is no risk of non-compliance with the TAA.

The new contract requires the PPV to provide FDA approved and TAA compliant WBPG. The delayed effective date of August 10, 2012, was to allow time for the PPV to implement purchasing channels for WBPG. We will schedule a review in the future to determine compliance with the contract terms and conditions regarding WBPG.

SUMMARY

Based on our review and our ongoing pre-award and post-award reviews of FSS contracts, we determined that open market purchasing through the PPV is impacted by several factors including products not on contract but needed to provide care, a growing number of product allocations and shortages necessitating purchasing products at non-contract prices, and purchasing products through the PPV for convenience instead of buying direct from manufacturers who do not participate in the PPV program. A growing number of products are not on contract because there is no requirement that manufacturers offer generic drugs on FSS contracts. In addition, a growing number of products are no longer manufactured in the United States or a designated country and thus cannot be offered on contract due to TAA requirements.

Conclusions

Our review of open market purchases found that the amount of open market purchases in FY 2011 was significantly less than originally estimated. In fact, it was quite difficult to quantify the actual dollars in open market purchases. This was in large part due to contract purchases inadvertently appearing as open market due to inconsistencies with the PPV data. Despite the data inconsistencies, we concluded that the PPV has charged the correct contract prices or at least has done a good job of correcting pricing errors through credits and rebills. In addition, due to product shortages and allocations, VA could not and did not always get contract pricing. It was not uncommon for pricing changes to be implemented months after the fact due to delays in contract modifications that result in retroactive price adjustments. The PPV has been able to correct any contract prices once VA has provided updated pricing data. We concluded that open market purchases were necessitated by the growing number of product shortages and backorder issues with manufacturers, as well as the growing number of generic products which vendors were not required to offer on FSS contracts.

We also concluded that the procedures implemented in November 2011 did not preclude or prohibit open market purchasing. Instead, open market purchases were shifted from the PPV account to other financing accounts. Furthermore, open market purchases have continued due to lack of training for VA Ordering Officers and the ability to circumvent procurement regulations when placing open market orders through the PPV or using known workarounds. We still have concerns that the new PPV contract will not be effective at limiting open market purchases as purchases have simply shifted to a different financing account or to provide fair and reasonable prices for WBPG.

Our review of open market purchasing trends under the new system was inconclusive because a large number of the products were actually on contract. In addition to reviewing the purchases identified in the FY 2011 data as open market, we sampled products identified as contract purchases. We did not find significant problems with overcharging. As with the open market products, we concluded that corrections were made over time as adjustments to the contract price were processed and entered into the PPV system.

Recommendations

We recommend that the Under Secretary for Health:

1. Require PBM to continue its monthly price adjudication process to include all sales transactions of both on contract and open market products through the PPV contract or other financing accounts. This process, in conjunction with the NAC, should be improved so that pricing errors are identified and resolved in a timelier manner.

2. Seek legislative changes to revise the annual FCP implementation date from January 1st to February 1st of each year to provide ample time to process the Non-FAMP data.

3. Ensure that the PBM price file uploaded into the PPV's ordering system uses the contract expiration date for all FCP prices versus the December 31st expiration date of FCP prices.

4. Block the purchase of approved WBPG if a comparable generic product is on contract.

We recommend that the Principal Executive Director for Acquisition, Logistics, and Construction:

5. Require the PPV to update its ordering system to ensure all transactions (especially rebills) for products on contract record the appropriate contract number in the database.

6. Require the NAC to award contract price changes in a timely manner to avoid backdating of price changes.

7. Determine the feasibility of creating an electronic interface to allow the price files to be updated with the vendor supplied Excel spreadsheets to eliminate the necessity for manually entering prices.

8 Seek legislative changes that would require manufacturers/dealers/resellers to offer generics on contracts.

9 Request the PPV contracting officer issue a modification to the PPV contract requiring monthly reporting of all open market purchases through the PPV contract/FastPay and open market purchases through other financing accounts.

We recommend that the Under Secretary for Health and the Principal Executive Director for Acquisition, Logistics, and Construction:

10. Require the PPV to update its ordering system interface to work with the CMOPs' system and require all facilities, including the CMOPs, to use McKesson Connect when placing orders in the future.

11. Prohibit purchasing through the PPV products sold on the FSS by manufacturers who do not participate in the PPV program. Instruct VA facilities to purchase these products directly from the FSS contractors or their authorized distributor at or below the FSS price.

12. For generic pharmaceuticals, use alternatives to long-term firm fixed-price contracts that are more consistent with commercial practices and provide an incentive to manufacturers to offer their products on contract.

13. Require the PPV to update its system to block VA Ordering Officers from placing open market orders. At a minimum, VA facilities should not be allowed to order open market products through the same web-based ordering system (McKesson Connect) used for the PPV program.

14. Provide training to Ordering Officers in allowable and unallowable procurement practices and revoke the warrant of any ordering officer found to be engaging in unallowable procurement practices.

15. Conduct a study to determine the impact TAA has in restricting access to generic pharmaceuticals and to what extent waivers or regulatory changes are necessary to ensure adequate product availability.

Appendix A

PRINCIPAL EXECUTIVE DIRECTOR FOR ACQUISITION, LOGISTICS, AND CONSTRUCTION COMMENTS

Department of Veterans Affairs

Memorandum

Date: SEP 24 2012

From: Principal Executive Director, Office of Acquisition, Logistics, and Construction (003)

Subj: OIG DRAFT REPORT: Review of Open Market Purchases under VA's Pharmaceutical Prime Vendor Contract Number V797P-1020 Awarded to McKesson Corporation (Report No. 12-01012-xxx) (VAIQ 7274052)

To: Director, Federal Supply Schedule Division, Office of Contract Review (55), OIG

1. The Office of Acquisition, Logistics, and Construction (OALC) reviewed and concurs with most recommendations in the Draft Report entitled, "Review of Open Market Purchases Under VA's Pharmaceutical Prime Vendor Contract Number V797P-1021 Awarded to McKesson Corporation." OALC offers the following in response to the Office of Inspector General's (OIG) initial request for comments.

2. The Office of Acquisition, Logistics and Construction (OALC) acknowledges that all of the OIG recommendations have shared responsibility as there is no clear delineated line of responsibility on most of the recommendations. As a result, OALC recommends that, while a clear "lead" office may exist, responses to the recommendations should represent the collaborative efforts of the Under Secretary for Health's Veteran Health Administration (VHA) Procurement and Logistics Office (PL&O) and/or Pharmacy Benefit Management Group (PBM) and OALC, most specifically the National Acquisition Center (NAC).

3. As such, OALC accepts responsibility for coordinating and consolidating responses to all 15 recommendations. OALC's NAC has coordinated with and vetted this response through VHA and PBM. The following provides OALC responses to each of the 15 OIG recommendations as summarized on pages 25 through 26 of your draft report:

OIG Recommendation 1: We recommended the Under Secretary for Health (VHA): Require PBM to continue its monthly price adjudication process to include all sales transactions of both on contract and open market products through the PPV contract or other financing accounts. This process, in conjunction with the NAC, should be improved so that pricing errors are identified and resolved in a timelier manner.

OALC/VHA Response: Concur. The VHA's PBM program office has not previously adjudicated open-market procurements made by VHA facilities. Purchase card holders and contracting officers are responsible for determining price reasonableness for open-market items at the time of purchase, reconciling price invoiced, and no national retrospective adjudication process is necessary. Purchase card holders reconcile purchases to assure vendor charges are correct for open-market orders up to $3,000. Open-market purchases above $3,000 are procured by Contracting Officers and after receipt of goods, payment is made by the Austin Finance Center based on line item pricing in the purchase order. PBM will continue its monthly review of Pharmacy Prime

SUBJECT: OIG DRAFT REPORT: Review of Open Market Purchases under VA's Pharmaceutical Prime Vendor Contract Number V797P-1020 Awarded to McKesson Corporation (Report No. 12-01012-xxx) (VAIQ 7274052)

Vendor (PPV) sales transaction. The OALC National Acquisition Center (NAC) contracting staff has responsibility for adjudicating PPV contract procurements and will continue to rely on PBM's monthly PPV price comparisons review. Currently, PPV contract adjudication timeliness is within three months, an allowable time frame, to allow for credits and rebills to be properly issued/reconciled.

Action Plan: OALC NAC is exploring options, including contracting for audit firm to review contract procurements under PPV and other just-in-time distribution programs. A report is to be provided and appropriate action is to be taken in response to the NAC findings by March 31, 2013.

Target Date for Completion: March 31, 2013

OIG Recommendation 2: We recommended the Under Secretary for Health (VHA): Seek legislative changes to revise the annual Federal Ceiling Price (FCP) implementation date from January 1st to February 1st of each year to provide ample time to process the Non-Federal Average Manufacturer Price (Non-FAMP) data.

OALC/VHA Response: Concur

Action Plan: The Public Law 102-585 Workgroup, which is comprised of PBM, NAC, Department of Veterans Affairs Office of General Counsel (OGC), and OIG representatives, will thoroughly analyze the recommendation, compile its findings, and, if feasible, identify an effective solution to provide ample process time for Non-FAMP negotiations and award. The participants on this workgroup have experience related to a similar recommendation, and that experience indicates that moving implementation date by one month may only move the problem. The workgroup will present its findings to OALC, VHA, and OGC leadership by March 31, 2013. It should be noted that any proposed change to the Public Law will require formal publicizing and time for public comment which may take several months beyond March 2013.

Target Date for Completion: March 31, 2013

Page 3

SUBJECT: OIG DRAFT REPORT: Review of Open Market Purchases under VA's Pharmaceutical Prime Vendor Contract Number V797P-1020 Awarded to McKesson Corporation (Report No. 12-01012-xxx) (VAIQ 7274052)

OIG Recommendation 3: We recommended the Under Secretary for Health (VHA): Ensure that the PBM price file uploaded into the PPV's ordering system uses the contract expiration date for all FCP prices versus the December 31 expiration date of FCP prices..

OALC/VHA Response: Concur

Action Plan: VHA PBM has been working with NAC's Federal Supply Schedule Service to ensure the appropriate contract expiration date is used for FCP. OALC NAC will ensure the price file uploaded to the PPV will contain the contract expiration dates, rather than the December 31 expiration date of FCP.

Target Date for Completion: June 30, 2013

OIG Recommendation 4: We recommended the Under Secretary for Health (VHA): Block the purchase of approved WBPG if a comparable generic product is on contract.

OALC/VHA Response: Non-Concur

OALC Comments: We believe this may cause another impediment to the order process now in place since the new PPV award. Putting a block on the WAC Based Priced Generics (WBPG) is a barrier that is not needed or required. As described in the OIG Draft Report, one of the most frequent reasons for purchasing a WBPG item is when the contracted item is out of stock. Blocking WBPG items would delay purchases and may affect patient care due to additional steps to purchase. Ordering Officers must be held accountable for appropriate decision making at time of order.

VHA Comments: Because this is a contract administration function, VHA defers to OALC NAC.

Action Plan: As part of Ordering Officer delegation, training has will continue to be provided to ordering officer. Refer to Recommendation 14.

Target Date for Completion: Ongoing.

Page 4

SUBJECT: OIG DRAFT REPORT: Review of Open Market Purchases under VA's Pharmaceutical Prime Vendor Contract Number V797P-1020 Awarded to McKesson Corporation (Report No. 12-01012-xxx) (VAIQ 7274052)

OIG Recommendation 5: We recommended the Principal Executive Director for Acquisition, Logistics, and Construction:
Require the PPV to update its ordering system to ensure all transactions (especially rebills) for products on contract record the appropriate contract number in the database.

OALC Response: Concur. Under the new PPV contract, McKesson is required to identify the appropriate invoice numbers pertaining to all orders issued against its PPV contract.

Responsible Office(s): OALC NAC, for PPV contract orders and issues.

Action Plan: OALC NAC will work with McKesson to ensure contact numbers are on appropriate PPV transactions.

Target Date for Completion: March 31, 2013

OIG Recommendation 6: We recommended the Principal Executive Director for Acquisition, Logistics, and Construction:
Require the NAC to award contract price changes in a timely manner to avoid backdating of price changes.

OALC Response**:** Concur. OALC NAC continues to strive to award price changes timely. However, should a contractor offer a price reduction with a back or retroactive date, we will not refuse the request as it will be in the best interest of the Government to accept.

Action Plan: OALC NAC will continue processing price changes (modification requests) in compliance with established procurement action lead time (PALT). Contracting staff will be held to PALT and held accountable.

Target Date for Completion: Ongoing

OIG Recommendation 7: We recommended the Principal Executive Director for Acquisition, Logistics, and Construction:
Determine the feasibility of creating an electronic interface to allow the price files to be updated with the vendor supplied Excel spreadsheets to eliminate the necessity for manually entering prices.

Page 5

SUBJECT: OIG DRAFT REPORT: Review of Open Market Purchases under VA's Pharmaceutical Prime Vendor Contract Number V797P-1020 Awarded to McKesson Corporation (Report No. 12-01012-xxx) (VAIQ 7274052)

OALC/VHA Response: Concur

Action Plan: OALC and VHA will consult with VA's Office of Information Technology ((OI&T)about establishing an electronic interface. The goal is to report findings about the establishment of an electronic interface or improving current processes by March 31, 2013. The plan selected will include timelines and milestones.

Target Date for Completion: Development of plan re-establishing an interface or improving current processes is expected by March 31, 2013

OIG Recommendation 8: We recommended the Principal Executive Director for Acquisition, Logistics, and Construction:
Seek legislative changes that would require manufacturers/ dealers/resellers to offer generics on contracts.

OALC/VHA Response: Concur.

Action Plan: The Public Law 102-585 Workgroup will develop the suggested legislative proposal by June 30, 2013. It should be noted that any proposed change to the Public Law will require formal publicizing and time for public comment which may take several months beyond June 2013.

Target Date for Completion: Legislative proposal to be drafted by June 30, 2013.

OIG Recommendation 9: We recommended the Principal Executive Director for Acquisition, Logistics, and Construction:
Request the PPV contracting officer issue a modification to the PPV contract requiring monthly reporting of all open market purchases through the PPV contract/FastPay and open market purchases through other financing accounts.

OALC Response: Non-concur. Open market purchases are not authorized through the new PPV contract.

Action: None required

Target Date for Completion: Completed.

Page 6

SUBJECT: OIG DRAFT REPORT: Review of Open Market Purchases under VA's Pharmaceutical Prime Vendor Contract Number V797P-1020 Awarded to McKesson Corporation (Report No. 12-01012-xxx) (VAIQ 7274052)

OIG Recommendation 10: We recommended the Under Secretary for Health and Principal Executive Director for Acquisition, Logistics, and Construction: Require the PPV to update its ordering system interface to work with the CMOPs' system and require all facilities, including the CMOPs, to use McKesson Connect when placing orders in the future.

OALC/VHA Response: Concur.

Action Plan: OALC NAC required this change under the new PPV contract. Implementation is complete for the ordering system. Work is ongoing for the receiving portion of McKesson Connect. The NAC contracting officer, with assistance from VHA Consolidated Mail Outpatient Pharmacy Officials (CMOP), is working with McKesson on implementation.

Target Date for Completion: September 30, 2013.

OIG Recommendation 11: We recommended the Under Secretary for Health and Principal Executive Director for Acquisition, Logistics, and Construction: Prohibit purchasing through the PPV products sold on the FSS by manufacturers who do not participate in the PPV program. Instruct VA facilities to purchase these products directly from the FSS contractors or their authorized distributor at or below the FSS price.

OALC/VHA Response: Partially Concur. Under the new PPV contract the system process has been tightened and locks out all non-PPV contract items. Only OALC NAC contracting staff has authority to add products to the PPV contract. However, this locking out order does not result in next day delivery of emergently/urgently needed medications. Next day delivery is mission critical to ensure Veterans receive the pharmaceuticals needed for their care. VHA will pursue developing, testing, and implementing a process that guarantees next day delivery for manufacturers who do not participate in the PPV program and meets the intent of the recommendation.

Responsible Office(s): OALC NAC and VHA PBM

Action Plan: OALC NAC will develop a procurement process to ensure mission critical next day delivery of pharmaceuticals on FSS contracts which are not available through the PPV. OALC NAC, in coordination with VHA PBM, will test the process. Once the process is successfully tested, it will be deployed nationally.

Page 7

SUBJECT: OIG DRAFT REPORT: Review of Open Market Purchases under VA's Pharmaceutical Prime Vendor Contract Number V797P-1020 Awarded to McKesson Corporation (Report No. 12-01012-xxx) (VAIQ 7274052)

Target Date for Completion: August 31, 2013

OIG Recommendation 12: We recommended the Under Secretary for Health and Principal Executive Director for Acquisition, Logistics, and Construction:
For generic pharmaceuticals, use alternatives to long-term firm, fixed-price contracts that are more consistent with commercial practices and provide an incentive to manufacturers to offer their products on contract.

OALC/VHA Response: Concur.

Responsible Office(s): OALC has lead with PBM support.

Action Plan: OALC NAC will award national contracts, possibly with incentives, to attract and establish long-term contract solutions.

Target Date for Completion: Ongoing dynamic process.

OIG Recommendation 13: We recommended the Under Secretary for Health and Principal Executive Director for Acquisition, Logistics, and Construction:
Require the PPV to update its system to block VA ordering officers from placing open market orders. At a minimum, VA facilities should not be allowed to order open market products through the same web-based ordering system (McKesson Connect) used for the PPV program.

OALC/VHA Response: Concur. Under the new PPV contract, VA customers cannot procure open market items under their PPV Fast Pay account number. The new PPV contract does not allow the mixing of contract items with open market items in the Fast Pay Account.

Target Date for Completion: Completed.

OIG Recommendation 14: We recommended the Under Secretary for Health and Principal Executive Director for Acquisition, Logistics, and Construction:
Provide training to ordering officers in allowable and unallowable procurement practices and revoke the warrant of any ordering officer found to be engaging in unallowable procurement practices.

OALC/VHA Response: Concur

Page 8

SUBJECT: OIG DRAFT REPORT: Review of Open Market Purchases under VA's Pharmaceutical Prime Vendor Contract Number V797P-1020 Awarded to McKesson Corporation (Report No. 12-01012-xxx) (VAIQ 7274052)

Action Plan: Training for all existing VHA ordering officers has been provided. The OALC NAC will provide ongoing training on a regular basis for new hired ordering officials as they are appointed. Ordering officers are not warranted; however, their delegation of authority to place orders can be revoked if they use unallowable procurement practices.

Target Date for Completion: Completed for existing ordering officers/on-going for new ordering officers.

OIG Recommendation 15: We recommended the Under Secretary for Health and Principal Executive Director for Acquisition, Logistics, and Construction: Conduct a study to determine the impact Trade Agreements Act (TAA) has in restricting access to generic pharmaceuticals and to what extent waivers or regulatory changes are necessary to ensure adequate product availability.

OALC Response: Concur. Currently, TAA requirements which are active at a certain dollar threshold based upon total estimated acquisition value, apply to Federal procurements. The U.S. Food and Drug Administration (FDA) have approved facilities with firms located in non-designated TAA countries such as in China and India and review the manufacturing process in order to assign FDA approval. We have seen an increase in pharmaceutical companies moving production of generics to locations outside the United States, primarily to non-TAA countries. VHA should conduct market research to determine the impact this is having on VA pharmacies. VHA should identify those products that were being provided from FSS contracts source and now available from non-TAA countries. OALC NAC is currently working with the General Services Administration to address non-availability determinations for non-TAA compliant products under the FSS Program.

VHA Response: Concur. VHA understands the effects of TAA on VA pharmacies and has identified products that are needed on contract. To address this, VHA has taken three important steps:

a. Developed a legislative proposal for waivers to the TAA during drug shortages;
b. Asked that FSS allow non-availability determinations for non-TAA compliant products to be placed on FSS; and
c. Provided procurement requests for national contracts.

Action Plan: The market research study is to be completed and results with recommendations are to be provided to OALC and VHA leadership by October 1, 2013.

Decisions pertaining to the next steps will be finalized by December 31, 2013. VHA will work with OALC to allow non-availability determinations for non-TAA compliant products to be placed on FSS.

Target Date for Completion: December 31, 2013.

4. Should you have any additional questions, please contact Mr. Craig Robinson, Associate Deputy Assistant Secretary for National Healthcare Acquisition (003A4), at (708) 786-5157, or via e-mail at: craig.robinson@va.gov.

Glenn D. Haggstrom

Appendix B

UNDER SECRETARY FOR HEALTH COMMENTS

Department of Veterans Affairs

Memorandum

Date: SEP 24 2012

From: Under Secretary for Health (10)

Subj: OIG Draft Report, Review of Open Market Purchases under VA's Pharmaceutical Prime Vendor Contract Number V797P-1020 Awarded to McKesson (VAIQ 7281028)

To: Principal Executive Director, Office of Acquisitions, Logisitics, and Construction (003)

Director, Federal Supply Schedule Division Office of Contract Review (55)

1. Thank you for the opportunity to review the draft report.

2. As mentioned in the memorandum from the Principal Executive Director, Office of Acquisition, Logistic, and Construction (OALC), the responses to the report's recommendations will require collaboration between Veterans Health Administration (VHA) and OALC. Therefore, VHA will work with OALC to address the action plan as outlined in the OALC memorandum.

3. If you have any questions, please contact Linda H. Lutes, Director, Management Review Service (10AR) at (202) 461-7014.

Robert. A. Petzel, M.D.

Appendix C

OIG CONTACT AND STAFF ACKNOWLEDGMENTS

OIG Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
Acknowledgments	Alyssa Witten

Appendix D

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